UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

ROBERT L. APTER, *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 3:22-cv-184 JUDGE JEFFREY V. BROWN

Defendants' Reply in Support of Their Motion to Dismiss the Amended Complaint

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INTRODUCTION

After receiving multiple reports of patients who required medical attention, including hospitalization, after self-medicating with ivermectin products intended for livestock,[1] FDA warned the public about certain risks related to using products containing ivermectin to prevent or treat COVID-19. Plaintiffs are doctors who prescribe ivermectin or promoted its use to prevent or treat COVID-19. In this suit, they seek to prevent FDA from communicating to the public its concerns about the potential risks of using ivermectin for that purpose. They allege that the statements cited in the Amended Complaint[2] caused them injuries, including interference with their "practice of medicine," being forced to resign from their jobs, and referrals for disciplinary proceedings.

Defendants' motion to dismiss showed that the Court does not have jurisdiction and that Plaintiffs failed to state a plausible claim for relief. Plaintiffs' Opposition fails to remedy these fatal defects.

Plaintiffs have not met their burden to show standing. Many of their alleged injuries are not adequate injuries in fact. For example, Plaintiffs argue that the cited statements interfered with the "practice of medicine," but Plaintiffs have not alleged that they have been unable to prescribe ivermectin to prevent or treat COVID-19. Plaintiffs also cannot rely on their patients' alleged injuries because

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[1] Contrary to Plaintiffs' assertion, Opp'n 9–10, the March 2021 version of the cited article stated that the U.S. Food and Drug Administration ("FDA") "received multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses," Ex. 19 at 2.

[2] The Amended Complaint identifies two versions of an article and two FAQs posted on FDA's website, two tweets linking to the article, an Instagram post, and a letter to two organizations (hereafter, the "cited statements").

they have not shown that their patients are unable or unwilling to seek relief themselves. None of the claimed injuries are traceable to the cited statements because they were caused by independent third-party conduct that was not a predictable response to those statements. Furthermore, the requested relief would not likely redress Plaintiffs' claimed injuries because, among other things, it would not likely cause the third parties to reverse their past decisions.

The Court also lacks jurisdiction because Plaintiffs have failed to show a waiver of sovereign immunity. In Count One, Plaintiffs invoke the narrow "ultra vires" doctrine, but they have not met their burden to show that FDA acted without any authority. The waiver of sovereign immunity in the Administrative Procedure Act ("APA") does not apply either because, among other reasons, the cited statements were not final agency action.

Finally, Plaintiffs have failed to state a claim because they did not present their issues to FDA before filing suit. Issue exhaustion ensures fairness to the agency and the efficient resolution of parties' claims, and Plaintiffs have not shown why their failure to exhaust their issues should be excused here.

ARGUMENT

I. Plaintiffs Have Not Shown that the Court Has Subject Matter Jurisdiction

A. Plaintiffs Have Not Met Their Burden to Show Standing

1. Plaintiffs Have Failed to Show an Adequate Injury in Fact for Many of Their Alleged Injuries

Plaintiffs' Opposition fails to show that, for many of their alleged injuries,[3]

[3] Although certain of Plaintiffs' alleged injuries, such as being forced to resign from their jobs, might be an adequate injury in fact, such injuries do not ultimately support standing because Plaintiffs have not shown that they are

Plaintiffs suffered an injury that is "concrete, particularized, and actual or imminent." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) Dkt. 25 ("Mot.") 12–15. By itself, Plaintiffs' "vague and conclusory" allegation that FDA "interfere[d] with the practice of medicine," Dkt. 12 ("Am. Compl.") ¶ 10, does not show "a concrete injury to Plaintiffs," Mot. 12. The allegation does not, for example, identify any particular action that Plaintiffs were prevented from taking, but instead alleges interference with an abstract concept.[4]

In a flawed attempt to show an injury in fact, Plaintiffs argue that 21 U.S.C. § 396 provides "a statutorily protected interest against FDA interference with their practice of medicine," which they define to include any "hindrance in the doctor-patient relationship, including actions that would 'deter off-label use.'" Opp'n 13–14. This argument fails for multiple reasons.

First, an alleged statutory violation does not necessarily show a concrete injury. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2205 (2021). Courts still must "independently decide whether a plaintiff has suffered a concrete harm under Article III." *Id.* Thus, even if Plaintiffs could show a violation of section 396, their vague and conclusory allegations concerning interference with the practice of medicine would still fail to show a concrete injury. *See Clapper*, 568 U.S. at 409; Mot. 12.

Second, section 396, by its plain language, concerns *devices*, not drugs like ivermectin. 21 U.S.C. § 396; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341,

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traceable to the cited statements or redressable by the requested relief. *See infra* pp. 8–16.

[4] Plaintiffs' allegations of more particular injuries, such as some pharmacists refusing to fill their patients' ivermectin prescriptions, are also inadequate for the reasons discussed below.

350 (2001) (noting that section 396 concerns "the marketing and distribution of *medical devices*" (emphasis added)). Plaintiffs are wrong to assert that the Fifth Circuit has interpreted section 396 "as applying to" drugs as well. Opp'n 3. Plaintiffs cite *U.S. ex rel. King v. Solvay Pharmaceuticals*, a False Claims Act case involving allegations of off-label marketing. 871 F.3d 318, 327–28 (5th Cir. 2017). The court noted that "FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use," and it supported that undisputed proposition with a "see" citation to section 396 and a parenthetical that quoted the statute's language regarding "device[s]." *Id.* at 328. In other words, the court cited the statute to provide indirect support for its statement about drugs while expressly recognizing that the statute applies to devices. The other cases Plaintiffs cite are unpersuasive for the same reason. *See* Opp'n 4 n.2. Similarly, the legislative history Plaintiffs cite fails to overcome the statute's plain language. *See id.* at 4 (quoting H.R. Rep. 105-399).

Third, even if section 396 applied to drugs, it would not support Plaintiffs' claimed statutory violation. It does not create any general "interest against FDA interference with the[] practice of medicine." Opp'n 13–14. Section 396 provides that "[n]othing in" the FDCA "shall be construed to limit or interfere *with the authority* of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (emphasis added). The information and recommendations in the cited statements did not "limit or interfere *with the authority*" of doctors to prescribe products containing ivermectin to prevent or treat COVID-19. 21 U.S.C. § 396. Plaintiffs do not allege

that the cited statements impaired their authority to prescribe ivermectin for that use. Indeed, the September 2021 version of the article and the April 2020 FAQ acknowledged that doctors have discretion to prescribe ivermectin products. Ex. 1 at 3;[5] Ex. 2 at 2; *see also* Ex. 27 at 23 (FDA Letter to Stakeholders).

FDA's longstanding position is that, in general, the agency does not regulate the practice of medicine, meaning that, with few exceptions, health care professionals generally may choose to prescribe or use a legally marketed human drug for an unapproved use when they judge that the unapproved use is medically appropriate for an individual patient. *See* Mot. 3 n.2. This position predates the 1997 enactment of section 396. *See, e.g.*, 52 Fed. Reg. 8798, 8803 (Mar. 19, 1987). But FDA's position regarding the "practice of medicine" has never cabined its ability to communicate with the public regarding the products it regulates. Indeed, the agency routinely communicates with the public, including warning of risks associated with an unapproved use of an approved drug. *See* Mot. 4.[6]

Plaintiffs argue that the cited statements interfered "many times" with their "ability to prescribe and administer ivermectin" to prevent or treat COVID-19, Opp'n 13–14, but the Amended Complaint does not allege *any* such instance. To

[5] Citations to exhibits refer to the exhibits to the Amended Complaint. Cited page numbers refer to the page numbers assigned by PACER.

[6] Amicus America's Frontline Doctors ("AFLDS") ignores the text of 21 C.F.R. § 312.2(d) in arguing that FDA's cited statements violated that regulation. AFLDS at 1, 3. FDA's regulations in 21 C.F.R. Part 312 govern clinical investigations of drugs for human use. Consistent with FDA's view of the practice of medicine, section 312.2(d) states that those regulations do "not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved under part 314 or of a licensed biological product." That regulation has no bearing on FDA's authority to communicate with the public.

the contrary, it confirms that Plaintiffs have continued to prescribe ivermectin for that purpose. *See, e.g.*, Am. Compl. ¶¶ 22, 26; Mot. 12.[7]

Plaintiffs' remaining attempts to meet their burden of alleging an "injury in fact" fare no better. Plaintiffs have not met the third-party standing requirement of showing a hindrance to their patients' ability to protect their own interests and thus cannot rely on their patients' alleged injuries, such as a delay in their patients' obtaining ivermectin because some pharmacies allegedly refused to fill their prescriptions or insurance companies allegedly refused to pay for those prescriptions. Mot. 14.[8] Plaintiffs assert that there has been a "groundswell of harm visited on anyone who challenges Defendants on ivermectin." Opp'n 15. But even if that were true, it would not demonstrate that Plaintiffs' patients are unable or unwilling to seek relief themselves. *See AIDS Healthcare Found., Inc. v. City of Baton Rouge/Par. of E. Baton Rouge*, No. 17-cv-229, 2017 WL 2899689, at *4 (M.D. La. July 7, 2017) (the "sensitivity of [AIDS patients'] identities and medical information" was insufficient to show that those patients were "unable or unwilling to bring" claims themselves).

Plaintiffs assert that there is a special exception to the rule against third-party standing for "providers to invoke the rights of their actual or potential patients." Opp'n 14–15 (quoting *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020)). But that principle was expressly limited to challenges by "abortion providers" to

[7] Plaintiffs' assertion that FDA "created a new industry standard that restricts doctors' abilities to prescribe certain off-label treatments for COVID-19" such as ivermectin, Opp'n 19 (quoting Ex. 28 at 2–3), is also at odds with the Amended Complaint.

[8] Defendants also argued that Plaintiffs cannot show standing based on alleged injuries to unnamed doctors and patients. Mot. 13–15. Plaintiffs do not respond to this argument and thus concede it. *See infra* p. 8.

"abortion-related regulations." 140 S. Ct. at 2118. Abortion is "a very special context," and "third party standing should not be extended to all cases where a physician seeks to assert some constitutional violation that the patients could bring themselves." *Massey v. Helman*, 35 F. Supp. 2d 1110, 1116 (C.D. Ill.), *aff'd*, 196 F.3d 727 (7th Cir. 1999).

Plaintiffs also cannot reframe some pharmacists' refusal to fill their patients' ivermectin prescriptions as an injury to themselves by arguing that it delayed their "ability to treat patients." Opp'n 12. Plaintiffs treated their patients by prescribing ivermectin to them, and they do not allege that they were unable to write such prescriptions. *See supra* pp. 5–6. Moreover, Plaintiffs cite no authority indicating that a doctor is injured by her patient's inability to *fill* a prescription. Indeed, courts have suggested that doctors are not injured in that circumstance. *See Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 544 (6th Cir. 2021) (observing in dicta that plaintiff "has not identified a harm to *physicians* merely because the drug may not be available to *patients*").

Finally, Apter's alleged referrals to the Arizona and Washington state medical boards, *see* Am. Compl. ¶¶ 18, 121, absent any allegation that he has actually been disciplined or that these disciplinary proceedings deprived him of due process or caused any other concrete injury, are not an adequate injury in fact. Mot. 13. Relying on *Kiser v. Reitz*, 765 F.3d 601, 608 (6th Cir. 2014), a First Amendment case, Plaintiffs argue that a plaintiff might adequately allege an injury in fact where he "has engaged in a course of [protected] conduct and the state has instructed him to stop or face disciplinary action." Opp'n 14. But Plaintiffs' reliance on *Kiser* is misplaced because they do not allege that FDA, or

any state entity, instructed Apter to stop prescribing ivermectin to prevent or treat COVID-19 or else face disciplinary action. Instead, Plaintiffs allege that an unknown entity referred Apter to the two state medical boards and "include[d]" copies of "FDA's publications,"[9] which does not show an injury in fact. Mot. 13; Am. Compl. ¶ 18.

2. Plaintiffs Have Failed to Show that Their Alleged Injuries Are Fairly Traceable to the Cited FDA Statements

Plaintiffs do not dispute that the cited statements "neither require[d] nor forb[ade] any action on the part of" Plaintiffs or anyone else, *Summers v. Earth Island Inst.*, 555 U.S. 488, 493–94 (2009), and did not direct that Plaintiffs or anyone else face any adverse consequences for prescribing or promoting ivermectin to prevent or treat COVID-19. Mot. 15. Plaintiffs also do not dispute that the Amended Complaint does not allege that Bowden's employer's decisions to "deride[]" her and "force[] [her] to resign," Am. Compl. ¶ 21, were based on the cited FDA statements, Mot. 15. Having failed to respond to those arguments, Plaintiffs concede them. *See Ark. v. Wilmington Tr. Nat'l Ass'n*, 2020 WL 1249570, at *5 (N.D. Tex. Mar. 16, 2020) ("Failure of a party to respond to arguments raised in a motion to dismiss constitutes waiver or abandonment of that issue at the district court level."); *Va. House of Delegates v. Bethune-Hill*, 139 S. Ct. 1945, 1951 (2019) ("[W]hen standing is questioned by . . . an opposing party, . . . the litigant must explain how the elements essential to standing are met.").

Plaintiffs' remaining alleged injuries rely on an indirect causal chain, in which the cited statements allegedly influenced the thinking of independent

[9] The Amended Complaint does not say whether there were additional bases for the referrals beyond prescribing ivermectin to treat COVID-19 or whether the referrals were supported only by FDA's publications.

third parties, and those third parties then allegedly injured Plaintiffs. Mot. 15–16. To establish traceability, Plaintiffs must show that the third-party decisions that allegedly harmed them were a "predictable" response to the cited FDA statements, *Daves v. Dallas County*, 22 F.4th 522, 543 (5th Cir. 2022) (quotations omitted); Mot. 16, but Plaintiffs have not made that showing, Mot. 15–17. Plaintiffs argue that those third-party actions were predictable because FDA must have intended the cited statements to "cause such reactions." Opp'n 16.[10] But the content of the cited statements makes plain that FDA's intent was to inform consumers, not to influence third parties to punish individual doctors.[11] *See, e.g.*, Ex. 1 at 3–4; Ex. 2 at 2; Ex. 3 at 2; Ex. 4 at 2; Ex. 6 at 2; Ex. 19 at 3.[12] The cited statements, moreover, did not state that doctors may not prescribe human-use ivermectin to prevent or treat COVID-19. Instead, the September 2021 article advised consumers that "[i]f your health care provider writes you an ivermectin

[10] Plaintiffs also argue that the "timing of [their] injuries immediately following when the FDA began its pressure campaign against ivermectin in earnest highlights the predominant role that issue played in their forced resignations." Opp'n 13; *see also id.* at 15. As an initial matter, the Amended Complaint does not provide precise dates for Plaintiffs' alleged injuries, let alone allege that they "immediately follow[ed]" the cited statements. Am. Compl. ¶¶ 10–43. And even if it did, that would not mean that Plaintiffs' alleged injuries are traceable to the cited statements. "Post hoc ergo propter hoc is not sound logic." *Tampa Times Co. v. NLRB*, 193 F.2d 582, 583 (5th Cir. 1952).

[11] For example, the cited statements do not propose or suggest any consequences for doctors who prescribe or promote ivermectin to prevent or treat COVID-19. It was not a predictable response to those statements for third parties to take the actions that allegedly harmed Plaintiffs, such as forcing them to resign. *See Daves*, 22 F.4th at 543.

[12] As Plaintiffs note, Opp'n 16, FDA also sent a letter to two organizations to "bring to [their] attention" information about "compounding pharmacies selling drug products containing ivermectin, claiming that they can treat or prevent COVID-19." Ex. 22 at 2. The letter did not state that doctors should not prescribe human-use ivermectin to prevent or treat COVID-19. Thus, the predictable response to this letter would not be to punish doctors for prescribing human-use ivermectin for their patients.

prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed," indicating that doctors have discretion to prescribe ivermectin products. Ex. 1 at 3. The article likewise recommended that patients talk to their doctors to determine their best treatment options. Ex. 1 at 4. Likewise, the April 2020 FAQ stated that "[y]ou should not take any medicine to treat or prevent COVID-19 unless it has been prescribed to you by your health care provider and acquired from a legitimate source." Ex. 2 at 2.[13]

Contrary to Plaintiffs' argument, this advice was not "buried" in the cited statements. Opp'n 17. In the FAQ, it appeared in the answer to the very first question, "Should I take ivermectin to prevent or treat COVID-19?," and in the article, it appeared under the headings "Here's What You Need to Know about Ivermectin" and "Options for Preventing and Treating COVID-19." Ex. 1 at 3–4; Ex. 2 at 2. Moreover, there is no indication that a reader would not review the entire cited statements, which are short. *See*, *e.g.*, Ex. 1 (3 pages); Ex. 2 (2 pages).

Plaintiffs' remaining arguments are equally unpersuasive. The fact that independent third parties referenced the cited FDA statements in taking actions that allegedly injured Plaintiffs does not show that those actions were predictable when FDA made the cited statements. Opp'n 17–18. And even if those third parties "are heavily influenced or feel bound by the FDA's actions,"[14] Opp'n 18;

[13] Similarly, even if Plaintiffs could rely on their patients' injuries, they still could not show traceability. For example, Plaintiffs have not shown that it was predictable that some pharmacies would refuse to fill ivermectin prescriptions since the September 2021 article and April 2020 FAQ acknowledged that doctors could prescribe ivermectin to prevent or treat COVID-19.

[14] Contrary to Plaintiffs' claim that independent third parties "feel bound" by FDA's recommendations, Opp'n 18, the Sentara Comprehensive COVID-19 Treatment Guidelines do not treat the cited statements as binding, Ex. 12 at 6. Instead, they list FDA among several organizations that "have issued statements

see also Dkt. 29-1 ("AAPS Br.") 6–9, it would not be predictable that they would respond to the cited statements by taking adverse action against Plaintiffs for prescribing or promoting ivermectin to prevent or treat COVID-19. As discussed above, the September 2021 article and April 2020 FAQ acknowledged doctors' discretion to prescribe ivermectin for that purpose. Ex. 1 at 3–4; Ex. 2 at 2.[15]

Plaintiffs argue that courts have "cit[ed] the FDA's statements as evidence about the effectiveness of ivermectin to treat COVID-19 and the appropriate standard of care" and "rel[ied] on those same statements and 'guidance' to determine legal standards." Opp'n 18. But the decisions Plaintiffs cite did not treat FDA's statements as dispositive; for example, they considered them together with statements by other organizations. *See*, *e.g.*, *DeMarco v. Christiana Care Health Servs., Inc.*, 263 A.3d 423, 435 (Del. Ch. 2021) (observing that "[t]reating COVID-19 with ivermectin is undisputedly contrary to generally accepted health care standards" and that "[p]reeminent institutions representing numerous facets of the national medical establishment, including the FDA, [the Centers for Disease Control and Prevention ("CDC")], [the American Medical Association], World Health Organization, and Infectious Disease Society of America, have criticized the use of ivermectin as a treatment for COVID-19").[16]

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recommending against the use of ivermectin for prevention or treatment of COVID-19," and they provide independent scientific reasons supporting that recommendation. Ex. 12 at 6.

[15] The cited tweets included links to the article. *See* Ex. 4; Ex. 7.

[16] The cases that the Association of American Physicians and Surgeons ("AAPS") cites in its amicus brief for the same purpose, AAPS Br. 6–7, also do not rely solely on FDA's statements. *See, e.g.*, *Frey ex rel. Frey v. Health-Michigan*, No. 359446, 2021 WL 5871744, at *1 (Mich. Ct. App. Dec. 10, 2021) (noting that FDA "has not approved ivermectin for use in treating COVID-19," that CDC "recommends against its use to treat COVID-19" and that "defendants' internal policy does not permit the use of ivermectin to treat COVID-19").

3. Plaintiffs Have Failed to Show that Their Alleged Injuries Are Likely Redressable by the Requested Relief

Plaintiffs fail to respond to and thus concede Defendants' arguments that they have not shown redressability regarding Marik and Bowden. *See Wilmington Tr.*, 2020 WL 1249570, at *5; *Va. House of Delegates*, 139 S. Ct. at 1951. Marik's state medical licenses are expired, and he has not alleged any intention to renew them. *See* Mot. 20. Also, Marik and Bowden were allegedly forced to resign for reasons other than prescribing or promoting ivermectin to prevent or treat COVID-19. *See id.* Plaintiffs also fail to respond to, and thus concede, Defendants' argument that Plaintiffs' requested declaration that the cited FDA statements "have no legal effect and do not bind health professionals or patients," Am. Compl. at 44, could not redress Plaintiffs' injuries because the cited statements were purely informational and did not purport to have any "legal effect." Mot. 19–20.

Plaintiffs incorrectly assert that redressability is "presumed" upon a finding of traceability, and they similarly argue that the fact that third parties have referenced FDA's statements supports redressability. Opp'n 20, 22. Although the traceability and redressability analyses sometimes overlap, the concepts are distinct and do not always point in the same direction. For example, even if governmental action is a "contributing factor in bringing about a specific harm," there is no redressability where "the undoing of the governmental action will not undo the harm[] because the new status quo is held in place by other forces." *Renal Physicians Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 489 F.3d 1267, 1278 (D.C. Cir. 2007). Here, even if the Court granted Plaintiffs' requested relief, Plaintiffs have not shown that the third parties that allegedly harmed them, such as their former employers, would likely reverse course, such as by rehiring them.

Contra Opp'n 22. Also, Marik can no longer practice medicine because he has no valid medical license. Moreover, Plaintiffs have not plausibly alleged that it is likely that any third parties would change their scientific understanding of the risks and benefits of using ivermectin to prevent or treat COVID-19 or the actions they took based on that understanding that allegedly harmed Plaintiffs. Mot. 18–19. This argument is not a "red herring," Opp'n 22: even if the cited statements were taken down, many other organizations have made statements advising against the use of ivermectin to prevent or treat COVID-19, such as Merck (the sponsor of Stromectol® (ivermectin)), CDC, the National Institutes of Health, and the World Health Organization. Mot. 19 (citing Ex. 12 at 6; Ex. 25; Am. Compl. ¶¶ 102–08).[17] In fact, Sentara, the hospital that formerly employed Marik, relied on Merck's statement, among others, in forming its conclusions about the use of ivermectin to prevent or treat COVID-19. Ex. 12 at 6.

Plaintiffs' argument that their requested relief would cause the medical community to "revert to th[e] norm" of supporting the off-label prescription of approved drugs, Opp'n. 21–22, is inapposite. The attitudes of third parties toward off-label prescription in general are irrelevant; what matters is what third parties will do regarding prescribing *ivermectin* to prevent or treat COVID-19.

Just as the alleged interference with the practice of medicine, by itself, is too vague and abstract to show a concrete injury, Plaintiffs' argument that the requested relief would remove such interference, Opp'n 21–22, is too vague and

[17] For example, even if Apter's referrals to state medical boards were an adequate injury, and even if "redressability is satisfied where the 'fear of future prosecution may be alleviated' by a favorable ruling," Opp'n 21, Plaintiffs still have not shown redressability because it is speculative how the requested relief might affect the state medical boards' future resolution of those referrals.

abstract to show redressability. As discussed above, Plaintiffs have not shown that their ability to prescribe ivermectin was ever impaired, and thus there is no such injury to redress. And even if the cited statements exerted pressure on Plaintiffs' professional judgment, Opp'n 21, Plaintiffs have not alleged that such pressure ever prevented them from prescribing ivermectin to prevent or treat COVID-19. Thus, taking down the cited statements and removing whatever pressure such statements generate would not redress any injuries. Mot. 18 n.16.

Plaintiffs also cannot show redressability regarding alleged injuries to their patients. *See* Opp'n 21–22. Even if Plaintiffs could rely on these alleged injuries to show an injury in fact, they still have not shown redressability because they have not shown that pharmacies, insurance companies, or the patients themselves would likely change their scientific understanding of the risks and benefits of using ivermectin to prevent or treat COVID-19 or the actions they took based on that understanding. *See supra* p. 13. In arguing that their "[p]atients will no longer be caught between the FDA's pressure campaign and Plaintiffs' advice," Opp'n 21, Plaintiffs ignore that many other organizations have issued public statements advising against the use of ivermectin to prevent or treat COVID-19.

The amicus briefs of AAPS and America's Frontline Doctors ("AFLDS") largely focus on the merits rather than standing. *See* AAPS Br.; Dkt. 35-1 ("AFLDS Br."). And although AAPS cites several cases in support of Plaintiffs' standing, these cases are inapposite. In *Tozzi v. U.S. Department of Health and Human Services*, 271 F.3d 301, 307 (D.C. Cir. 2001), *see* AAPS Br. 10–11, the court held that a manufacturer of dioxin products had standing to challenge an agency report that classified dioxin as a "known" carcinogen under a classification

scheme mandated by statute, and which was intended by Congress "to serve as the federal government's authoritative statement" on the carcinogenicity of various chemicals. *Id.* at 309. The classification followed an elaborate process that included publication in the Federal Register and public hearings, and it triggered legal obligations under federal and state regulations. *Id.* at 304, 308, 310. The court observed that the classification would likely lead "state and local agencies to regulate products containing dioxin" and "healthcare companies to reduce or end purchases of" those products, especially since the term "carcinogen" is "inherently pejorative and damaging." *Id.* at 309. Additionally, no other federal agency had labeled dioxin a "known" carcinogen. *Id.* at 309–10.

Here, by contrast, the cited statements provide nonbinding recommendations, and Plaintiffs do not allege that they automatically triggered legal obligations under federal or state law. Moreover, Plaintiffs have not shown that third parties would likely respond to the cited statements by taking the actions that allegedly harmed Plaintiffs. *See supra* pp. 12–14. Furthermore, the more nuanced message of the September 2021 article and the April 2020 FAQ, acknowledging doctors' discretion to prescribe ivermectin to prevent or treat COVID-19, is unlike the unambiguously negative designation "known" carcinogen. And other federal agencies, such as CDC, have recommended against the use of ivermectin to prevent or treat COVID-19. *See supra* p. 13.

Similarly inapposite is *Meese v. Keene*, 481 U.S. 465 (1987), *see* AAPS Br. 11, which held that the plaintiff had standing to challenge the government's classification of films as "political propaganda" because that classification would likely harm Plaintiffs' reputation if he exhibited the films. *Id.* at 472–77. Here, the

cited statements do not say that doctors should not prescribe ivermectin to prevent or treat COVID-19. Finally, contrary to AAPS's assertion that *Community for Creative Non-Violence v. Pierce* ("*CCNV*"), 814 F.2d 663 (D.C. Cir. 1987), "found that homeless men had standing to challenge" an agency report "based on the likelihood of being turned away from a homeless shelter due to it," AAPS Br. 9–10, the court held that these plaintiffs failed to show traceability or redressability. *CCNV*, 814 F.2d at 666–70.

B. Plaintiffs Have Not Met Their Burden to Show a Waiver of Sovereign Immunity

"It is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction." *United States v. Mitchell*, 463 U.S. 206, 212 (1983). Plaintiffs argue that they do not need to show a waiver of sovereign immunity with respect to Count One because it is an "ultra vires claim" and that, regardless, the Court has jurisdiction over all of their claims because Plaintiffs have met the requirements for the APA's waiver of sovereign immunity. Opp'n 23–28. Both arguments are meritless.

First, Plaintiffs argue that they do not need to show a waiver of sovereign immunity for Count One because FDA acted "without any authority whatever." Opp'n 23–24. Plaintiffs invoke the ultra vires doctrine, which is "intended to be of *extremely* limited scope." *Griffith v. FLRA*, 842 F.2d 487, 493 (D.C. Cir. 1988) (emphasis added). A plaintiff's mere "claim of error" is "not sufficient" to establish a court's jurisdiction on an ultra vires theory. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 690 (1949). Rather, a plaintiff must "allege facts sufficient to establish" that the government acted "'without any authority whatever,' or without any 'colorable basis for the exercise of authority.'" *Danos v.*

Jones, 652 F.3d 577, 583 (5th Cir. 2011) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 n.11 (1984)).

Here, Plaintiffs have not made the required showing that FDA lacked "any authority whatever" or a "colorable basis" to make the cited statements. *Id.* They do not argue that FDA lacks the authority to make public statements in general. Plaintiffs instead argue that FDA's authority to make the cited statements is limited by 21 U.S.C. § 396, a provision that is directed to devices, not drugs, and does not implicate FDA's communications. *See* Opp'n 24; *supra* pp. 3–5. Plaintiffs have thus not met the demanding standard required to review Count One under the "extremely limited" ultra vires doctrine. *Griffith*, 842 F.2d at 493.

Second, the APA's waiver of sovereign immunity is not available for any of Plaintiffs' claims. As an initial matter, Plaintiffs assert that an agency's "purely informational statements" meet the APA's definition of a "rule" and are therefore reviewable agency action. Opp'n 24–28. Although Plaintiffs note the definition is broad, *id.*, it is not boundless and does not apply to the cited statements. Agencies "make rules when they announce principles of general applicability and future effect." *Walmart Inc. v. U.S. Dep't of Just.*, 21 F.4th 300, 308 (5th Cir. 2021) (applying 5 U.S.C. § 551(4)). The cited statements did no such thing: they did not "appl[y]" to any particular party and did not purport to have any "future effect." 5 U.S.C. § 551(4). Instead, they provided nonbinding recommendations to the public at large.[18] Plaintiffs do not argue that the cited

[18] The Fifth Circuit cases Plaintiffs cite in support of their agency action argument are inapt. *See* Opp'n 24–25. *Avoyelles Sportsmen's League, Inc. v. Marsh* concerned whether the EPA had engaged in legislative or interpretative rulemaking, not whether the determination at issue met the definition of "rule." 715 F.2d 897, 908–09 (5th Cir. 1983). The agency action requirement was not at

statements meet the definition of any other kind of agency action, thus, the APA's waiver of sovereign immunity does not apply.

Even if Plaintiffs could adequately allege "agency action," they still fail to adequately allege that the cited statements caused them to suffer a "legal wrong" or an "adverse[] affect[]." *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 489 (5th Cir. 2014) (citing 5 U.S.C. § 702). As discussed above, Plaintiffs have not alleged a concrete injury that is fairly traceable to the cited statements. *See supra* pp. 2–11; *contra* Opp'n 25.

As to the APA claims, Plaintiffs have failed to show a waiver of sovereign immunity for the additional reason that the cited statements do not meet either requirement for "final" agency action. *See Alabama-Coushatta*, 757 F.3d at 488–89. First, the statements did not reflect the consummation of the agency's decisionmaking process as to any issue. *Bennett v. Spear*, 520 U.S. 154, 178 (1997). Even Plaintiffs characterize the March 2021 version of the article (Exhibit 19) as a "first draft," Opp'n 17, and rather than stating FDA's definitive, final position on the use of ivermectin to prevent or treat COVID-19, the statements were expressly tentative: they were based on "[c]urrently available data," said that "[a]dditional testing is needed," and indicated that "[c]linical trials" are "ongoing." Ex. 1 at 3; Ex. 2 at 2. Plaintiffs' attempt to show finality regarding the other statements cherry picks sections of the cited statements and ignores the many sections that reflect FDA's tentative position. *See* Opp'n 26.

A final agency action must also "be one by which rights or obligations have

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issue in *Data Marketing Partnership, LP v. U.S. Department of Labor*, so the court's reference to a Department of Labor information letter being "non-final agency action" sheds no light on whether the cited statements here constituted agency action. 45 F.4th 846, 855 (5th Cir. 2022).

been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 178 (quotation omitted). In *Data Marketing Partnership, LP v. U.S. Department of Labor*, for example, the plaintiffs challenged a Department of Labor advisory opinion that "bound" the agency and "withdrew its previously held discretion," which was "textbook final agency action." 45 F.4th 846, 854 (5th Cir. 2022). The court contrasted the advisory opinion with "information letters," which were not final because they were "informational only" and did not bind the agency. *Id.* at 855. Like the information letters in *Data Marketing*, the cited statements here were not final because they were informational only and did not narrow FDA's discretion or bind the agency in any way.

Without citing any authority, Plaintiffs contend that "legally binding effects are not necessary to render agency action 'final' for the purposes of judicial review when the action in question is expressly prohibited by the statute regardless of such effects." Opp'n 27. But final agency action must "be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 178 (quotation omitted). This standard is not necessarily met simply because a statute has allegedly been violated. Plaintiffs have not plausibly alleged such a violation. *See supra* pp. 3–5.

Plaintiffs also argue that, even without "direct consequences," the cited statements were "binding as a practical matter" and "thus final" because they "dictate[d] a 'norm,'" and private parties could be "reasonably led to believe that failure to conform" to that norm would "bring adverse consequences." Opp'n 26–27 (quoting *Texas v. EEOC*, 933 F.3d 433, 442 (5th Cir. 2019)). In *EEOC*, the Fifth Circuit held that an agency guidance document can be "final" if the agency

creates a "norm or safe harbor," where the *agency* can take adverse action against a private party if that party fails to comply with the norm. 933 F.3d at 442–44; *see also*, *e.g.*, *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597–99 (2016). Here, by contrast, Plaintiffs do not allege that the cited statements caused them to fear enforcement by *FDA*, but instead allege that *third parties* might take adverse actions against them if they fail to comply with the purported "norms." FDA's statements are not "binding as a practical matter" simply because third parties might independently decide to take adverse actions against parties that do not comply with them. *EEOC*, 933 F.3d at 442. The legal consequences relevant to the analysis laid out in *EEOC* flow from the agency to third parties, not independent third parties to other third parties. *Id.*

Plaintiffs' and the amici's position is all the less credible because they argue that doctors' authority to prescribe approved drugs for unapproved uses is well established. *See* Opp'n 3-4; AAPS Br. 3; AFLDS Br. 4. Plaintiffs cannot plausibly argue that anyone could "reasonably believe" that FDA effectuated a binding change to that well-established practice through a tweet saying "You are not a horse. You are not a cow. Seriously, y'all. Stop it," a similar Instagram post, or an article containing recommendations and no mandatory language. In short, the cited statements did not purport to alter the existing "legal regime." *Contra* Opp'n 27 (citing *State v. Biden*, 10 F.4th 538, 550 (5th Cir. 2021)).

Finally, while Plaintiffs assert that the "effects" of agency action need not "direct[ly]" affect them, Opp'n 27, the supposed "norm" they cite did not have a legal effect on anyone. For example, the September 2021 article acknowledged that doctors have discretion to prescribe ivermectin for preventing or treating

COVID-19, *see* Ex. 1 at 3–4, which underscores how Plaintiffs' alleged injuries resulted from private, third-party decisions.

II. Plaintiffs Forfeited Their Arguments by Declining to Raise Them With FDA Prior to Filing this Lawsuit

Even if the Court had jurisdiction, the Amended Complaint should be dismissed because the issues raised therein were never presented to FDA for administrative resolution. Contrary to Plaintiffs' claim, Defendants did not argue that Plaintiffs should be "required to raise their claims through a 'citizen petition'" or any particular administrative remedy. Opp'n 28. Instead, Defendants invoked the principle of "issue exhaustion" and argued that, regardless of the method, "the agency should be given the first chance" to apply its expertise and discretion to the *issues* raised in the Amended Complaint. Mot. 28–29 (quoting *McKart v. United States*, 395 U.S. 185, 194 (1969)). As discussed in Defendants' motion, the Fifth Circuit recently applied issue exhaustion in *Palm Valley Health Care v. Azar*, 947 F.3d 321 (5th Cir. 2020). Mot. 29.

As in *Palm Valley*, Plaintiffs failed to present a question to the agency prior to litigation and that, as a result, the court "cannot consider [that] question." *Id.* at 328. Plaintiffs make no attempt to distinguish that case. Nor do they contest the many benefits of issue exhaustion. *See* Mot. 28–29.

Instead, Plaintiffs argue that the citizen petition process "do[es] not apply" to their ultra vires claim because FDA only "has primary jurisdiction to make the initial determination on issues within its statutory mandate." Opp'n 28 (quoting 21 C.F.R. § 10.25(b)). But the provision Plaintiffs cite is not a limitation on the Citizen Petition process and, contrary to Plaintiffs' suggestion (Opp'n 29), it strains credulity that Plaintiffs' requested relief, such as removing an article,

would fail to qualify as "any . . . form of administrative action" under 21 C.F.R. § 10.25(a). *See also Koretoff v. Vilsack*, 707 F.3d 394, 397–98 (D.C. Cir. 2013). Similarly, Plaintiffs' unsupported argument that the citizen petition process "is aimed at scenarios" where a party can petition FDA before the agency takes action, Opp'n 29, is incorrect: the citizen petition process has been used to ask FDA to reconsider decades-old positions and actions, including its position on the scope of its own authority. *See*, *e.g.*, *Henley v. FDA*, 77 F.3d 616 (2d Cir. 1996); *Action on Smoking & Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). Plaintiffs further argue that the "ongoing negative effects" of the cited statements warrant "prompt judicial review," Opp'n 30, but they ignore the 26 months that elapsed between the first statement Plaintiffs cite (Ex. 2) and the date they filed this lawsuit, time which could have been used to raise their issues directly to FDA.

Plaintiffs further assert that requiring them to present their claims to FDA would violate 5 U.S.C. § 704 because it would "in effect" require them to pursue a "form of reconsideration." Opp'n 30. But that section concerns whether an agency action is "final," 5 U.S.C. § 704, not the question of issue exhaustion.

If the Court concludes it has subject matter jurisdiction, and as an alternative to dismissal on issue exhaustion grounds, Defendants would not object to a stay of this case to allow Plaintiffs to present their issues to FDA for administrative resolution in the first instance.

CONCLUSION

For the foregoing reasons, and those stated in Defendants' motion, the Amended Complaint should be dismissed for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

October 21, 2022

/s/ Isaac C. Belfer
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